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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,049	07/30/2004	Bernd Stahl	STAH3008/REF	2144
23364	7590	10/19/2007		
BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314			EXAMINER KRISHNAN, GANAPATHY	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 10/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/502,409 <b>049</b>	<b>Applicant(s)</b> UEHATA, YOSHIHARU	
	<b>Examiner</b> Ganapathy Krishnan	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2007.
- 2a) ☐ This action is **FINAL**:                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 14-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The amendment filed 7/24/2007 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-13 have been canceled.
2. New Claims 14-28 have been added.
3. Remarks drawn to rejections under Double patenting, 35 USC 101, 112, first and second paragraphs

Claims 14-28 are pending in the case. The new rejections contained herein below are made of record.

#### ***Specification***

The objection to the Abstract has been overcome by amendment.

#### ***Claim Objections***

Claim 26 is objected to because of the following informalities: Claim 26 recites a first structural formula, which is labeled as (I) and (II) and further recites another structural formula which is labeled (II). Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of Claims 1-9 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, has been rendered moot by cancellation of the said claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 10-13 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising the carbohydrate of formula I, does not reasonably provide enablement for a composition comprising the carbohydrate of formula I and further carbohydrates which are different, active agents(s), ingredients, auxiliaries, moisturizing agents, thickening agents, flavoring agents sweetening agents and carriers, method of treatment and prevention of immunomodulation, immunosuppression and infections, has been rendered moot by cancellation of claims 10-13.

The said rejection is being maintained for new claims 14-23, 25 and 27-28. New claims 14-23, 25 and 27-28 have been amended as method claims and recite the same limitations as above. Applicants have traversed the enablement rejection made of record earlier by arguing that the amended claims refer to the definitions of sialic acid derivatives. The specification sets forth that the inventive carbohydrates are efficient inhibitors or receptor analogs and explains the mechanism of operation of the carbohydrates. Based on this and the level of one of skill in the art the specification is enabling.

Applicants' arguments are not found to be persuasive. Just defining the instant carbohydrates as O-acyl derivatives and the mechanism of operation without representative examples does not enable the methods of treatment and prevention as instantly claimed. The rejection is being maintained for new claims 14-23, 25 and 27-28.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 1-13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been rendered moot by cancellation of the said claims.

The following rejections are made of record necessitated by amendment.

Claims 14-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "several" recited in claims 14 and 25 is a relative term which renders these and all other claims in which the said term is recited indefinite. The term "several" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 14 recites structural formula (I) in which V is defined as an OH or carbohydrate residue or a carrier T and the carbohydrate or carrier is further defined as formula (II). This means that that the carrier and carbohydrate residue are one and the same. The term carrier is also defined by the letter T, which means that it could be any moiety. It is not clear what applicants intend. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by

"such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 14 recites the broad recitation carrier T, and the claim also recites carbohydrate residue, which is the narrower statement of the range/limitation. This lack of clarity is also seen in claim 26. Claim 14, at line 4 recites, at least one carbohydrate unit of formula (II) as shown in formula (I). This recitation is confusing. Clarification is needed.

Claim 15, which depends from claim 14, recites that the carrier T is a peptide, a protein, a polymer of a biopolymer. But according to parent claim 14 the carrier is defined by formula (II). It is not clear what applicants intend. Also, according to the recitation of the parent claim 14, V can be a carbohydrate residue or a carrier T. But according to the recitation of dependent claim 15, the compound can have both the carbohydrate residue and the carrier T. This is not seen to further limit the parent claim. This recitation is also seen in claim 27 and in claim 27, wherein (in claim 27) T is defined as lipophilic compounds.

Claim 15(I) recites N-glycolyl. Do applicants intend the glycol residue or do applicants intend N-glycosyl? This recitation is also seen in claim 27 I).

In claim 17 it is not clear what head group(s) means.

Claim 20 recites, "at least 1mg of formula I per kg of body weight". It is not clear what applicants intend by the said recitations. The recitation, "at least" indicates that more than the

recited amount may be used. Since 1mg is the lower limit, the upper limit is not defined. This renders the claim indefinite.

Claim 22 recites limitations within parentheses. It is not clear if these limitations are part of the claim. If they are part of the claim the parentheses should be removed.

Claim 25 recites the terms, "further active agent(s), such ingredients", without a definition. In the absence of the specific names or chemical structure, the identity of the said agents and ingredients would be difficult to describe and the metes and bounds of said agents and ingredients applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims. It is not clear what applicants mean by the recitation, "which is known and suited for the corresponding composition".

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of Claim 10 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 7 of copending Application No. 10/148,193('193 application) is being maintained for reasons of record. Applicants have requested that the filing of a Terminal Disclaimer be held in abeyance till allowable subject matter is indicated in one of the applications. The rejection will be dropped after the filing and approval of the Terminal Disclaimer.

The rejection of Claim 10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6 and 9-10 of U.S. Patent No. 6,576,251 ('251 patent) is being maintained for reasons of record.

Applicants have traversed the rejection arguing that the '251 patent deals with carbohydrates mixtures wherein the carbohydrates have different chain lengths and furthermore, fucose has to be present. Fucose is not mentioned in the instant application and hence the rejection should be withdrawn. This is not found to be persuasive. The carbohydrates of the instant invention and those of the '251 patent have chain lengths that overlap. Moreover, claims 1, 6 and 9-10 of the '251 patent do not require the presence of fucose. The rejection is being maintained.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:



(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilbert et al (WO 00/46379; document cited in IDS of 30 July 2004).

Gilbert et al teach a carbohydrate comprising (labeled GT1a-, the second saccharide sequence from the bottom in Figure 4), which has all the components as recited in instant formula (I). It also has a neuraminic acid-5-acetate (acyl derivative) attached to the galactose (on the right). This is the same as the Hex attached to X in instant formula (I), wherein Hex is Galactose (Gal) and X is Neuraminic acid -5-acetate. The glucose moiety on the right side of the

sequence is the carbohydrate residue or the carrier as instantly claimed and n is 1. Gilbert teaches pharmaceutical compositions of his compounds suitable for different modes of administration. The compositions include other agents/auxiliaries like buffers tonicity adjusting agents. The compositions can be administered for therapeutic treatment of a variety of conditions in doses ranging from 0.5mg to about 40g (page 41, line 20 through page 43, line 20) and suggests the administration of the oligosaccharides as immunogen (immunomodulation or suppression). However, Gilbert et al do not exemplify the method of immunomodulation or immunosuppression or treatment of infections specifically using the oligosaccharide described above, a food or dietetic composition comprising the oligosaccharides and the other derivatives as instantly claimed. But one of skill in the art reading the teachings of Gilbert will recognize that such oligosaccharides have the potential for use in methods of treatment as instantly claimed since their use in the treatment of a variety of conditions is suggested by Gilbert (page 41, lines 20-26). Since Gilbert also suggests oral administration, one of skill in the art will also recognize the use of these oligosaccharides in food compositions.

It would have been obvious to one of skill in the art at the time the invention was made to make the carbohydrates and derivatives of instant formula (I) and their compositions and use them in a method of treatment as instantly claimed since the use of carbohydrates that are structurally close to instant formula (I) is suggested in the prior art as a therapeutic agent for a variety of conditions.

One of skill in the art would be motivated to use the compounds as instantly claimed since they are close structural analogs and would look for such analogs with a high therapeutic index and would also expect them to work with a reasonable expectation of success.

**Conclusion**

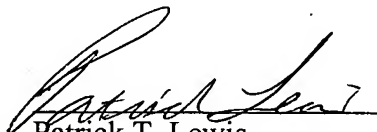
Claims 14-28 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

  
Patrick T. Lewis  
Primary Patent Examiner  
Art Unit 1623